

received by the HCFA official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the HCFA official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon re-application of the entity), a fair hearing officer, or a HCFA official designated to hear such appeals, determines that the entity qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which HCFA has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§ 405.877 Appeal of a categorization of a device.

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under sec-

tion 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subparts I–Q—[Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of HCFA.

Administrator's review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and § 405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and § 405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and § 405.1835.

Date of filing and *date of submission of materials* mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

Date of receipt means the date on the return receipt of "return receipt requested" mail, unless otherwise defined in this subpart.

Intermediary determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the